EPA Jacket 83529-87

PROCESSING REQUEST

Reg # 83529-87 Decision # 529894				
Description: NEW PRODUCT				
Electronic Label & Letter (see PPLS): Non Electronic Label & Letter (Scanning required):				
□ Dated: 0 3 7 □ Dated:				
Only one label type should be selected				
Other Materials Sent (see jacket):				
New CSF(s) Dated: $7/13/17$				
Other:				
File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.				
Reviewer: SARAH MEADOWS				
Division:				
Phone: 347-0505 Date: 11/30/17.				



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.

Washington, D.C. 20460

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

83529-87

10/13/17

Term of Issuance:

Conditional

Name of Pesticide Product:

SHARDA ACETOCHLOR 29% + ATRAZINE 14.5% CS

Name and Address of Registrant (include ZIP Code):

Sharda USA LLC c/o Wagner Regulatory Associates, Inc. PO Box 640, Hockessin, DE 19707

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

FPA Form 8570-6

- 2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Acetochlor GDCI-121601-1660

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

- 3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 83529-87."
- 4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

Basic CSF dated 7/13/2017

If you have any questions, please contact Sarah Meadows by phone at 703-347-0505, or via email at meadows.sarah@epa.gov.

Attachment

RESTRICTED USE PESTICIDE

Due to ground and surface water concerns. For retail sale to and use only by Certified Applicators, or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

GROUP 5 15 HERBICIDES

Sharda Acetochlor 29% + Atrazine 14.5% CS

ABN: Etcetra

An Encapsulated Herbicide for Weed Control in Corn (Field, Production Seed, Silage, Sweet, and Popcorn), Grain Sorghum (milo), and Miscanthus or Other Non-Food Bioenergy Crops.

ACTIVE INGREDIENTS:	WT. BY %
*Acetochlor, 2-chloro-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)acetamide	29.0%
**Atrazine, 2-chloro-4-(ethylamino)-6-(isopropylamino)-s-triazine and related triazines	14.5%
OTHER INGREDIENTS:	<u>56.5%</u>
TOTAL:	100.0%

^{*}Contains 324 grams per liter or 2.63 lbs. per U.S. gal. of the active ingredient acetochlor.

KEEP OUT OF REACH OF CHILDREN CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

	FIRST AID
IF ON SKIN OR CLOTHING:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.
and the second s	 Sensitized persons should avoid further contact and reuse of contaminated clothing.
	HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information concerning this product, call your poison control center at 1-800-222-1222.

[Optional referral statements when booklets and container labels are used:

See Panel for First Aid Instructions and booklet for complete Precautionary Statements and Directions for Use.

See label booklet for complete Precautionary Statements, Directions For Use, and Storage and Disposal.

See label booklet for additional Precautionary Statements, Directions For Use, and Storage and Disposal.

See label booklet for complete Directions For Use.]

EPA Reg. No. 83529-IT

EPA Est. No. XXXXX-XX-XXX

Manufactured	for:		^	^
Sharda	USA	LLC	[S]	$\left(\mathbf{U}\right)$
			_	

7217 Lancaster Pike, Suite A Hockessin, Delaware 19707

Net Contents:	gal	s./	L.

ACCEPTED

10/13/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2000 07

83529-87

^{**}Contains 161 grams per liter or 1.31 lbs. per U.S. gal. of the active ingredient atrazine and related triazines.

29% + Atrazine 14.5% CS ABN: Etcetra Initial Draft Label Page **2** of **15**

PRECAUTIONARY STATEMENTS

Sharda Acetou

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Prolonged or repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Mixers, loaders, applicators, and other handlers must wear:

- · Long-sleeved shirt and long pants
- Chemical-resistant gloves such as barrier laminate, butyl rubber ≥14 mils, nitrile rubber ≥14 mils, neoprene rubber ≥14 mils, polyvinyl chloride (PVC) ≥14 mils, or Viton® ≥14 mils
- Shoes and socks
- chemical-resistant apron when mixing/loading, cleaning up spills, or cleaning equipment, or otherwise exposed to the concentrate. See ENGINEERING CONTROL STATEMENT for additional requirements.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing or other absorbent materials that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

ENGINEERING CONTROL STATEMENT

When applicators use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(5)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because an enclosed cab is being used, applicators must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

USER SAFETY RECOMMENDATIONS

Users should:

- · Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Atrazine can travel (seep or leach) through soil and can enter groundwater which may be used as drinking water. Atrazine has been found in ground water. Users are advised not to apply atrazine to sand and loamy sand soils where the water table (ground water) is close to the surface and where these soils are very permeable, i.e., well drained. Your local agricultural agencies can provide further information on the type of soil in your area and the location of groundwater.

Groundwater contamination may be reduced by diking and flooring of permanent liquid bulk storage sites with an impermeable material.

This product is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Runoff and drift from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters.

This chemical demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the groundwater is shallow, may result in groundwater contamination. Acetochlor has properties that may result in surface water contamination via dissolved runoff and runoff erosion. Practices should be followed to minimize the potential for dissolved runoff and/or runoff erosion.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

ANY USE OF THIS PRODUCT IN AN AREA WHERE USE IS PROHIBITED IS A VIOLATION OF FEDERAL LAW. Before using this product, you must consult the Atrazine Watershed Information Center (AWIC) to determine whether the use of this product is prohibited in your watershed. AWIC can be accessed through www.atrazine-watershed.info or 1-866-365-3014. If use of this product is prohibited in your watershed, you may return this product to your point of purchase or contact Sharda USA, LLC for a refund.

Not for Use in Nassau and Suffolk Counties in New York State.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Byran T. Banks Sept-28-2017 Problem 9/26/2017

SIMILARITY CLINIC

September 28, 2017

Subject:

SHARDA ACETOCHLOR 29% + ATRAZINE 14.5% CS

EPA File Symbol 83529-IT

DP Barcode: 442918 Action Code: R300

PC Codes: 080803 (Atrazine: 29%)

121601 (Acetochlor: 14.5%)

From:

Byron T. Backus, Ph.D., Toxicologist

CITAB

Registration Division (7505P)

Through:

P.V. Shah, Ph.D., Branch Chief

CITAB

Registration Division (7505P)

To:

Sarah Meadows/Reuben Baris, RM 25

Herbicide Branch

Registration Division (7505P)

Applicant:

SHARDA USA LLC

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
121601 Acetochlor*: 2-chloro-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)	
acetamide	29.0%
080803 Atrazine**: 2-chloro-4-(ethylamino)-6-(isopropylamino)-s-triazine	
and related triazines	14.5%
Other Ingredients:	<u>56.5%</u>
TOTAL:	100.0%

^{*}Contains 324 grams per liter or 2.70 lbs per U.S. gal. of the active ingredient acetochlor.

<u>ACTION REQUESTED</u>: "Please determine if the proposed product 83529-IT is similar to 524-511. I have attached the proposed CSF, proposed label, cover letter and data matrix. I have also attached the cited CSF and label..."

^{**}Contains 161 grams per liter of 1.34 lbs per U.S. gal. of the active ingredient atrazine and related triazines.

<u>BACKGROUND</u>: The material received includes a cover letter (dated May 26, 2017), an application for pesticide registration stating that this product is similar or identical in composition and labeling to EPA Reg. No. 524-511, a data matrix (dated May 26, 2017) using cite-all to address the acute toxicity data requirements, a proposed label, a proposed basic CSF (dated July 13, 2017), and a CSF for the cited product, and the last accepted label (August 24, 2011)

COMMENTS AND RECOMMENDATIONS:

- 1. After examining the proposed basic CSF for 83529-IT and the CSF (dated May 19, 2014) for the cited product (524-511), CITAB concludes that, despite a number of compositional and/or percentage differences involving the other ingredients, they are toxicologically similar.
- 2. Both the proposed and cited products are labeled as restricted use "Due to ground and surface water concerns."
- 3. The registrant has proposed precautionary and first aid labeling statements for 83529-IT that are essentially identical to those of EPA Reg. No. 524-511. These proposed statements are acceptable. These statements are also consistent with the following acute toxicity profile for the cited product, as stated in a TRB memorandum dated June 10, 1999 for 524-LRR:

Acute Oral LD ₅₀	IV	Acceptable
Acute Dermal LD ₅₀	IV	Acceptable
Acute Inhalation LC ₅₀	IV	Acceptable
Primary Eye Irritation	IV	Acceptable
Primary Skin Irritation	IV	Acceptable
Dermal Sensitizatjon	Positive	Acceptable

- 4. The proposed Personal Protective Equipment (PPE) statements for 83529-IT are acceptable.
- 5. The acute toxicity data requirements for the registration of 83529-IT have been satisfied by citeall.
- 6. The proposed ingredient statement for 83529-IT includes a footnote indicating that it contains 324 grams/liter or 2.70 lbs/gallon of the active ingredient acetochlor and 161 grams/liter or 1.34 lbs/gallon of the active ingredient atrazine. According to the CSF this product has a density of 1.0858 g/mL (or 9.056 lb/gallon). Using the percentages of actives as declared on the label it would then contain 1.0858 g/mL x 1000 mL/L x 0.29 = 314.9 grams acetochlor/liter (2.63 lbs acetochlor/gallon) and 1.0858 g/mL x 1000 mL/L x 0.145 = 157.4 grams atrazine/liter (1.31 lbs atrazine/gallon). The footnote should be revised accordingly.
- 7. The proposed basic CSF for 83529-IT must also be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

huertr 9-22-

FEE

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: <u>D442889</u>; FILE SYMBOL No.: <u>83529-IT</u>; PRODUCT NAME: <u>Sharda Acetochlor 29% + Atrazine 14.5% CS</u>; <u>DECISION No.:529894</u>; PC Code(s): <u>080803</u>, <u>121601</u>; ACTION CODE: <u>R300</u>; FOOD

Use: Yes; COMPANY: Sharda USA LLC

DATE OUT:

July 22, 2017

SUBJECT:

End Use Product Chemistry Review

Product Name: Sharda Acetochlor 29 % + Atrazine 14.5% CS

FROM:

Shyam Mathur, Ph. D

Team Leader

Chemistry, Inerts & Toxicology Assessment Branch (CITAB) /RD (7505P)

TO:

Sarah Meadows / Reuben Baris, RM 25; Herbicide Branch / RD (7505P)

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product Sharda Acetochlor 29% + Atrazine 12.5% CS. The registrant has submitted a CSF for basic formulation dated July 13, 2017 and the supporting group A & group B product chemistry data with MRID No(s). 50278401 to 50278404. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 524-511. CITAB has been asked to determine the acceptability of the proposed basic CSF, the supporting product chemistry data and also determine similarity to the registered product.

SUMMARY OF FINDINGS:

- 1. Name of Active Ingredient(s): Acetochlor (29.0%) and Atrazine (14.50%)
- 2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes give the registration number of the cited product.

EPA Reg. No: 524-511

- 3. All of the source materials of the active ingredient are derived from registered sources-[X] Yes [] No
- All inert ingredients have been screened by CITAB (Inert group) and found to be approved for the proposed labeled uses.

DP BARCODE No.: <u>D442889</u>; FILE SYMBOL No.: <u>83529-IT</u>; PRODUCT NAME: <u>Sharda Acetochlor 29% + Atrazine 14.5% CS</u>; <u>DECISION No.:529894</u>; PC Code(s): <u>080803, 121601</u>; ACTION CODE: <u>R300</u>; FOOD Use: <u>Yes</u>; COMPANY: <u>Sharda USA LLC</u>

5.	Confidential Statement of Formula(s):						
	[X] Basic - Dated: 07-13-2017; Re-submitted - Dated:						
	[] Alternate CSF – All Dated: ; Re-submitted alt CSF – Dated:						
	Alternate CSF(s) complies with 40CFR§152.43: [] Yes; [] No; [X] NA						
6.	Pr	oduct label					
	a.	Ingredient statement: Nominal concentration of Al listed on CSF(s) concurs with product label (PR Notice 91-2). [X] Yes; [] No; if not, explain below:					
	Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient) [X] Yes; [] No; if not, explain below:						
		Metallic equivalent: [] Yes [X] NA Soluble arsenic: [] Yes [X] NA Isomeric ratios: [] Yes [X] NA Acid Equivalent: [] Yes [X] NA: acid equivalent = %					
	b.	Health related sub statements: Product contains?					
z		Petroleum distillate at > 10%: [] Yes [X] No [] NA Methanol at > 4%: [] Yes [X] No [] NA Sodium nitrate/Sodium nitrite [] Yes [X] No [] NA					
_	C.	 c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown? [] Yes; [X] No 					
		Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)? [] Yes; [] No; [X] NA; if not, explain below					
	d. Label requires an additional Storage and Disposal statement:						
	[] Yes; [X] No; if yes explain below:						

DP BARCODE No.: <u>D442889</u>; FILE SYMBOL No.: <u>83529-IT</u>; PRODUCT NAME: <u>Sharda Acetochlor 29% + Atrazine 14.5% CS</u>; <u>DECISION No.: 529894</u>; PC Code(s): <u>080803, 121601</u>; ACTION CODE: <u>R300</u>; FOOD Use: <u>Yes</u>; COMPANY: <u>Sharda USA LLC</u>

7. Group A: Product Chemistry Data submitted

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title	Study Title		ubmitted	CITAB's Assessment	MRID Nos.	
			Yes	No	of Data	Cited	
830.1550	Product Ider	ntity & Composition	Х		Α	50278401	
830.1600	produce the		x		А	50278401	
830.1650	Description of formulation process		х		Α	50278401	
830.1670	Discussion on the formation of impurities		x		A	50278401	
830.1700	Preliminary analysis			X	NA		
	Vide Product No.	Standard certified limits	x		Α		
	Certified limits	Proposed Limits					
830.1750	(158.350)	Justification for wider limits				Basic CSF dated 07-13-2017	
	Enforcement analytical method					50278402 Submitted along with storage	
830.1800			X		Α	stability study	

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

DP BARCODE No.: <u>D442889</u>; FILE SYMBOL No.: <u>83529-IT</u>; PRODUCT NAME: <u>Sharda Acetochlor 29% + Atrazine 14.5% CS</u>; <u>DECISION No.:529894</u>; PC Code(s): <u>080803</u>, <u>121601</u>; ACTION CODE: <u>R300</u>; FOOD Use: <u>Yes</u>; COMPANY: <u>Sharda USA LLC</u>

8. Group B: Product chemistry data submitted

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	White liquid at 20°C	А	50278402
830.6315	Flammability	>100°C	Α	50278403
830.6316	Explodability	Waiver request. TS is not potentially explosive.	A	50278404
830.7000	рН	8.2 at 22°C (1% w/v aqueous solution)	А	50278402
830.7300	Density (units)	1.0858 g/cc (9.05 lbs/gal) at 20°C	A	50278402
830.7100	Viscosity (Rotational)	218.95-512.89 cps at 20°C 367.05 to 1205.74 cps at 40°C	A	50278402
830.6317	Accelerated Storage stability	Stable in HDPE containers when stored for 2 weeks at 54°C.	A	50278402
830.6320	Accelerated Corrosion characteristics	TS did not show any corrosive effects on AI, polyethylene, & Zn. Corrosive to Cu & Fe. 2 weeks at 54°C.	A	50278402
		TS was found to be compatible with water, fire extinguishing agents, reducing agents, oxidizing agents and, except for Ammonium dihydrogen phosphate that a physical		
830.6314	Oxidation/reduction	state change was observed (it becomes solid).	A	50278403

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable; I = In progress

DP BARCODE No.: <u>D442889</u>; FILE SYMBOL No.: <u>83529-IT</u>; PRODUCT NAME: <u>Sharda Acetochlor 29% + Atrazine 14.5% CS</u>; <u>DECISION No.:529894</u>; PC Code(s): <u>080803, 121601</u>; ACTION CODE: <u>R300</u>; FOOD Use: <u>Yes</u>; COMPANY: <u>Sharda USA LLC</u>

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the end-use product and has concluded that:

A.	Substantial similarity to the cited product (Reg. No. 524-511) from Product chemistry view point [X] Similar [] Not similar, give reasons: [] Not Applicable
B.	Confidential Statement of formula
	1. Basic CSF (dated: 07-13-2017) [X] Acceptable [] Not Acceptable: [] Not Applicable
	2. Alternate CSF's (all dated:) [] Acceptable [] Not Acceptable: [X] Not Applicable
C.	Group A Product Chemistry Data
	[X] Acceptable [] Acceptable with the exception of the guideline: [] Not acceptable [] Not required [] Data cited
D.	Group B Product chemistry data
	 [X] Acceptable [] Not acceptable [] Acceptable with the exception of the guidelines: [] Not required [] Data cited for the guidelines [X] Waiver requests for the guideline 830.6316 (explodability): [X] Acceptable; [] Not Acceptable; [] Not Applicable
E.	Product Label/Draft Label: Recommendations – Yes []; No [X]
F	or for suggested by Tox ren-w 10-12-1)

Inert ingredient information may be entitled to confidential treatment

Meac	lows.	Sarah

From:

Anna Armstrong < Anna@wagnerreg.com>

Sent:

Thursday, July 13, 2017 10:19 AM

To:

Meadows, Sarah

Cc:

Baris, Reuben; Anna Armstrong

Subject:

RE: EPA File Symbol 83529-IT - Sharda Acetochlor 29% + Atrazine 14.5% CS

PESUBMISSION

Attachments:

83529-XX Basic CSF 13July2017.docx.pdf

Hi Sarah,

Please find attached the revised CSF. Please let me know if you have any additional comments or questions.

Thanks so much and take care,

Anna

From: Meadows, Sarah [mailto:Meadows.Sarah@epa.gov]

Sent: Wednesday, July 12, 2017 10:01 AM
To: Anna Armstrong <Anna@wagnerreg.com>
Cc: Baris, Reuben <Baris.Reuben@epa.gov>

Subject: RE: EPA File Symbol 83529-IT - Sharda Acetochlor 29% + Atrazine 14.5% CS

Hi, Anna. Sorry for the delayed response.

To answer your question, yes. What you propose below will be acceptable.

Thanks,

Sarah

From: Anna Armstrong [mailto:Anna@wagnerreg.com]

Sent: Thursday, July 06, 2017 3:46 PM

To: Meadows, Sarah < Meadows.Sarah@epa.gov >

Cc: Baris, Reuben <<u>Baris.Reuben@epa.gov</u>>; Anna Armstrong <<u>Anna@wagnerreg.com</u>> Subject: FW: EPA File Symbol 83529-IT - Sharda Acetochlor 29% + Atrazine 14.5% CS

Hi Sarah,

Sharda has responded and has a question.

Please let me know and I will send the revised CSF.

Thanks so much and take care, Anna

From: Meadows, Sarah [mailto:Meadows.Sarah@epa.gov]

Sent: Wednesday, June 28, 2017 3:27 PM **To:** Anna Armstrong < <u>Anna@wagnerreg.com</u>> **Cc:** Baris, Reuben < <u>Baris.Reuben@epa.gov</u>>

Subject: EPA File Symbol 83529-IT - Sharda Acetochlor 29% + Atrazine 14.5% CS

Hi, Anna. Per our phone discussion, I have attached the inert status report that you requested. Let me know if you have any other questions.

Thanks,

Sarah

Mattingly, Sean

From:

Anna Armstrong < Anna@wagnerreg.com >

Sent:

Tuesday, June 13, 2017 10:43 AM

To:

Mattingly, Sean

Cc:

Anna Armstrong; Kt Woodall

Subject:

RE: EPA Submission Sharda Fluroxypyr 12.3% + Clopyralid 11.3% EC (EPA Reg. No.

83529-IA)

Attachments:

83529-XXXXX.20170526.V1.pdf (83529-1T)

Follow Up Flag:

Follow up

Flag Status:

Flagged

Submitter responded for product 83529-17 from an email [sent for product 83529-14

Hi Sean,

Thank you. I received a note from the manufacturer of the inerts that they are pulling together the information. I requested that they send it today - but I'm not sure if they will meet the timeline. If they do not, I will have them forward it to Reuben.

In the meantime, I greatly appreciate you replacing the submitted label with the one attached.

Thanks so much and take care,

Anna

From: Mattingly, Sean [mailto:Mattingly.Sean@epa.gov]

Sent: Tuesday, June 13, 2017 10:34 AM

To: Anna Armstrong < Anna@wagnerreg.com>

Subject: RE: EPA Submission Sharda Fluroxypyr 12.3% + Clopyralid 11.3% EC (EPA Reg. No. 83529-IA)

Hi Anna,

Yes, I can accept a revised label also.

Thanks,

Sean Mattingly

From: Anna Armstrong [mailto:Anna@wagnerreg.com]

Sent: Monday, June 12, 2017 3:20 PM

To: Mattingly, Sean < Mattingly. Sean@epa.gov> Cc: Anna Armstrong < Anna@wagnerreg.com>

Subject: RE: EPA Submission Sharda Eluroxypyr 12.3% + Clopyralid 11.3% EC (EPA Reg. No. 83529-IA)

Hi Sean

I am still working with manufacturer to provide confirmation of the inerts. I am hopeful to have feedback by tomorrow.

I wanted to ask – we noticed a slight error in the product label. Would it be possible to send a revised label to you at this time?

Thanks in advance and take care,

Anna

From: Mattingly, Sean [mailto:Mattingly.Sean@epa.gov]

Sent: Wednesday, June 7, 2017 9:36 AM

To: Anna Armstrong < <u>Anna@wagnerreg.com</u>> **Cc:** Ashe, Anthony < <u>Ashe.Anthony@epa.gov</u>>

Subject: EPA Submission Sharda Fluroxypyr 12.3% + Clopyralid 11.3% EC (EPA Reg. No. 83529-IA)

Dear Anna Armstrong,

My name is Sean Mattingly and I am a contractor with the EPA. I am contacting you in regard to your submissions in support of the product Sharda Flaroxypyr 12.3% + Clopyralid 11.3% EC (EPA Reg. No. 83529-IA). We have found a few deficiencies with the submissions that need to be addressed:

1. There is an issue with an inert ingredient listed on the CSF. Please see attached Inert Clearance Status Form for more information.

Please indicate if you intend on fixing the corrections and send all necessary documents to this e-mail address by 6/14. After that day, please send directly to the PM. If you have any questions, please do not hesitate to contact me.

Sean Mattingly

Contractor, US EPA 2777 S. Crystral Drive, S-4822 Arlington, VA 22202 703-347-0501 Email: mattingly.sean@epa.gov

Mattingly, Sean

From:

Mattingly, Sean

Sent:

Wednesday, June 07, 2017 1:45 PM

To: Cc: Anna Armstrong Ashe, Anthony

Subject:

EPA Submission Sharda Acetochlor 29% + Atrazine 14.5% CS ABN: Etcetra (EPA Reg. No.

83529-IT)

Attachments:

83529-IT Inert Clearance Status Form.docx

Dear Anna Armstrong,

My name is Sean Mattingly and I am a contractor with the EPA. I am contacting you in regard to your submissions in support of the product Sharda Acetochlor 29% + Atrazine 14.5% CS ABN: Etcetra (EPA Reg. No. 83529-IT). We have found a few deficiencies with the submissions that need to be addressed:

1. There is an issue with multiple inert ingredients listed on the CSF. Please see attached Inert Clearance Status Form for more information.

Please indicate if you intend on fixing the corrections and send all necessary documents to this e-mail address by 6/13. After that day, please send directly to the PM. If you have any questions, please do not hesitate to contact me.

Sean Mattingly

Contractor, US EPA 2777 S. Crystral Drive, S-4822 Arlington, VA 22202 703-347-0501 Email: mattingly.sean@epa.gov

Please read instructions on reverse before	ing forr	n.			Form	AL	EL JM	B No. 20	70-006	30. Appro	val exp	oires 05-31-98
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	I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. Received Received											
both under applicable law.			**************************************		STOREST CONTRACT	Proposition of the second	t. Det Statistic Control of the			(Star	mped)	
2. Signature	2	3. Title										
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Anna Armetrona		May 26, 20	4-7									I

This is a reproduction of EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Submitted Electronically

May 26, 2017

Document Processing Desk (REGFEE) Attn: Reuben Baris, PM 25 Registration Division U.S. Environmental Protection Agency Office of Pesticide Programs (7505P) Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, Virginia 22202-4501



Wagner Regulatory Associates, Inc. P.O. Box 640 7217 Lancaster Pike, Suite A Hockessin, Delaware 19707

Subject: Sharda Acetochlor 29% + Atrazine 14.5% CS ABN: Etcetra EPA Company No. 83529

Application to register a new end-use product - (PRIA R300)

Dear Mr. Baris:

Wagner Regulatory Associates, Inc., as agent for Sharda USA LLC, is requesting registration of the above referenced product. In support of this request, the following documents and studies are being submitted electronically via the EPA CDX PSP portal.

- Letter from Sharda USA LLC appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4)
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35), internal and public versions
- Data Transmittal Document
- Formulators Exemption (8570-27)
- · Data as outlined in the transmittal document
- Draft label
- Certification with Respect to Label Integrity
- Receipt confirming payment of fee for PRIA R300 \$1,582.

Thank you in advance for your efforts in reviewing this submission. Please do not hesitate to contact me by email at anna@wagnerreg.com or by phone at 302-510-0039 should you have any questions.

Respectfully submitted,

Anna Armstrong

Agent for Sharda USA LLC

Enclosures

DATA TRANSMITTAL DOCUMENT

1.

Name and Address of Submitter
Sharda USA LLC
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707

2.

Regulatory Action In Support Of Which This Package Is Submitted
Application for New Registration
Sharda Acetochlor 29% + Atrazine 14.5% CS ABN: Etcetra

3. Transmittal Date May 26, 2017

4. **List of Submitted Studies**

50278401	Sharda Acetochlor 29% + Atrazine 14.5% CS Product Identity and Composition, Description of Materials, Description of Formulation Process, Preliminary Analysis, Discussion of Impurities, and Certified Limits. OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750
50278402	Acetochlor 29% + Atrazin 14.5% CS - Physical-Chemical Properties and Accelerated Storage Study, Study No. E17005, OPPTS: 830.1800, 830.6302, 830.6303, 830.6304, 830.6313, 830.6317, 830.6320, 830.7000, 830.7100, 830.7300, 830.7520
50278403	Sharda Acetochlor 29% + Atrazin 14.5% CS - Flash Point And Oxidizing Properties, Study No. E17041, OPPTS: 830.6314, 830.6315
50278404	Sharda Acetochlor 29% + Atrazine 14.5% CS Product Chemistry - Group B: Request for Waiver for Certain Physical/Chemical Properties Data. OPPTS 830.6313; 830.6316; 830.6319; 830.6321; 830.7050; 830.7200; 830.7220; 830.7370; 830.7520; 830.7550; 830.7560; 830.7570; 830.7840; 830.7860; 830.7950

Company Official:	
Anna Armstrong Authorized Agent	Signature Signature
Company Name: Sharda USA LLC	
Company Contact:	
Anna Armstrong	(302) 510-0039
Authorized Agent	Phone





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

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Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.					
Certification with Respect to Citation of Data					
Applicant's/Registrant's Name, Address, and Telephone Number Sharda USA LLC, P.O. Box 640, Hockessin, DE 19707		EPA Registration Number/File Symbol 83529-XX			
Active Ingredient(s) and/or representative test compound(s) Acetochlor + Atrazine	Date May 26, 2017				
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158 Terrestrial food Crops and non food crops	Product Name Sharda Acetochlor 29% + Atrazine 14.5% CS ABN: Etcetra				
NOTE: If your product is a 100% repackaging of another purchased EPA-register submit this form. You must submit the Formulator's Exemption Statement (EPA Formulator's Exemption Statement)	ed product labeled for 8570-27).	or all the same uses on your label, you do not need to			
I am responding to a Data-Call-In Notice, and have included with this form a be used for this purpose).	list of companies se	ent offers of compensation (the Data Matrix form should			
SECTION I: METHOD OF DATA SUP	PORT (Check one m	nethod only)			
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under the	g the selective method of support (or cite-all option e selective method), and have included with this form a d list of data requirements (the Data Matrix form must be			
SECTION II: GENERAL	OFFER TO PAY				
	[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements] I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.				
SECTION III: CERT	TFICATION				
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.					
I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.					
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.					
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.					
l certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					
Signature Quality	Date 05/26/2017	Typed or Printed Name and Title Anna Armstrong, Agent			

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

WASHINGTON, D.C. 20460

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Date: May 26, 2017 Applicant's/Registrant's Name and Address: Sharda USA LLC c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707 Sharda Acetochlor 29% + Atrazine 14.5% CS ABN: Etcetra

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
830.1550, 830.1600, 830.1650, 830.1670, 830.1750	Product Identity & Composition/ Description of Materials used to Produce the Product/Description of Formulation Process/Discussion of Formation and Toxicity of Impurities, Certified Limits	50278401	Sharda USA LLC	Own	
830.1700	Preliminary Analysis	50278401	Sharda USA LLC	Own	
830.1800	Enforcement Analytical Method	50278402	Sharda USA LLC	Own	
830.6302	Color	50278402	Sharda USA LLC	Own	
830.6303	Physical State	50278402	Sharda USA LLC	Own	
830.6304	Odor	50278402	Sharda USA LLC	Own	
830.6313	Stability to Normal & Elevated Temperatures	50278402	Sharda USA LLC	Own	
830.6314	Oxidation/Reduction	50278403	Sharda USA LLC	Own	
830.6315	Flammability	50278403	Sharda USA LLC	Own	
830.6316	Explodability	50278404	Sharda USA LLC	Own	
830.6317	Storage Stability	50278402	Sharda USA LLC	Own	
830.6319	Miscibility	50278404	Sharda USA LLC	Own	
830.6320	Corrosion Characteristics	50278402	Sharda USA LLC	Own	
830.6321	Dielectric breakdown voltage	50278404	Sharda USA LLC	Own	
830.7000	pH	50278402	Sharda USA LLC	Own	
830.7050	UV/Visible Light Absorption	50278404	Sharda USA LLC	Own	
830.7100	Viscosity	50278402	Sharda USA LLC	Own	
830.7200	Melting Point	50278404	Sharda USA LLC	Own	
830.7220	Boiling Point	50278404	Sharda USA LLC	Own	
830.7300	Density/Relative Density	50278402	Sharda USA LLC	Own	
830.7370	Dissociation Constant in Water	50278404	Sharda USA LLC	Own	
830.7520	Particle Size, fiber length & diameter distribution	50278404	Sharda USA LLC	Own	

Signature
Name and Title
Anna Armstrong, Agent
May 26, 2017



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

WASHINGTON, D.C. 20460

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Date: May 26, 2017 Applicant's/Registrant's Name and Address: Sharda USA LLC c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707 Ingredient: Acetochlor BPA Reg No./ File Symbol: 83529-XX Product: Sharda Acetochlor 29% + Atrazine 14.5% CS ABN: Etcetra

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7550; 7560; 7570	Partition Coefficient (n-Octanol/Water)	50278404	Sharda USA LLC	Own	
830.7840; 7860	Water Solubility/Solubility in Organic Solvents	50278404	Sharda USA LLC	Own	
830.7950	Vapor Pressure	50278404	Sharda USA LLC	Own	
870.1100	Acute Oral Toxicity	CITE ALL	E.I. DuPont Nemours, Wilmington, DE	Pay	
870.1200	Acute Dermal Toxicity		Monsanto Company, Washington, DC	1	
870.1300	Acute Inhalation Toxicity		Gowan Comp, Yuma, AZ	1 1	
870.2400	Primary Eye Irritation		Adama Agan, Raleigh, NC		
870.2500 870.2600	Primary Dermal Irritation Dermal Sensitization		Drexel Chemical Company, Memphis, TN		
870.2000	Definal Sensitization		Loveland Products Inc, Greeley, CO		
			Albaugh LLC, Valdosta, GA		
	N		Dow Agrosciences LLC, Indianapolis, IN		
			Makhteshim Agan of N.A., Raleigh, NC		
			Monsanto Company, Washington, DC		
			Spray Drift Task Force, Washington, DC		
			Outdoor Residential Exp. Task Force, Wash, DC		
			Ag. Reentry Task Force, Washington, DC		
			FIFRA Endangered Species Task Force,		
			Lakewood, WA		
			Ag. Handler Exposure Task Force, Macon, MO		
			Generic Endangered Species Task Force, Gig	1	
			Harbor, WA		
			Syngenta Crop Protection, LLC, Greensboro, NC		
			Bayer Cropscience LP, RTP, NC		
			FMC Corporation, Philadelphia, PA		

Signature
Name and Title
Anna Armstrong, Agent
May 26, 2017



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

WASHINGTON, D.C. 20460

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Date: May 26, 2017		EPA Reg No./ File Symbol: 83529-XX	Page 3 of 3
Applicant's/Registrant's Name and Address:	Sharda USA LLC c/o Wagner Regulatory Associates, Inc. P.O. Box 640	Product:	
gredient: Acetochlor	Hockessin, DE 19707	Sharda Acetochlor 29% + Atrazine 14.5% CS A	BN: Etcetra

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Scotts Company, Marysville, OH	Pay	
			Winfield Solutions, LLC., St. Paul, MN	1 1	
			Land O'Lakes Purina Feed LLC, St. Louis, MO		
			BASF Corporation, RTP, NC	1	
			Chemisco, St. Louis, MO	1	
			Adama Makhteshim LTD, Raleigh, NC	1	
			Oxon Italia S.P.A., Gig Harbor, WA		
			Tessenderlo Kerley, Inc., Gig Harbor, WA	1	
		220	Mey Corporation, Washington, DE	1	

Footnotes:

Signature
Name and Title
Anna Armstrong, Agent
May 26, 2017

Product ingredient source information may be entitled to confidential treatment

Form approved. OMB No. 2070-0060, 2070- __/, 2070-0107, 2070-0122, 2070-0164.



United States Environmental Protection Agency Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address EPA File Symbol/Registration Number 83529-XX Sharda USA LLC c/o Wagner Regulatory Associates, Inc. Product Name P.O. Box 640 Sharda Acetochlor 29% + Atrazine 14.5% CS ABN: Etcetra Hockessin, DE 19707 Date of Confidential Statement of Formula (EPA Form 8570-4)

05/26/2017

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Acetochlor + Atrazine

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).
- (3) Indicate by checking (A) or (B) below which paragraph applies:
- (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.
- (4) The following active ingredients in this product qualify for the formulator's exemption.

	Source	
Active Ingredient	Product Name	Registration Number
Acetochlor		
Atrazine		
ignature	Name and Title	Date
Mouland	Anna Armstrong, Agent	05/26/2017
PA Form 8570-27 (Rev. 06-2004)		Copy 1 – EPA

Copy 2 - Applicant copy



Receipt

Your payment is complete

Pay.gov Tracking ID: 262LJR3R Agency Tracking ID: 75251752451

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card Payment Amount: \$1,582.00

Transaction Date: 05/25/2017 01:22:13 PM EDT

Payment Date: 05/25/2017 Registration Number:

Company Name: Sharda USA LLC

Company Number: 83529 Action Code: R300

Account Information

Cardholder Name: Cheryl Wagner Card Type: American Express Card Number: *********2008

Email Confirmation Receipt

Confirmation Receipts have been emailed to:

carrie@wagnerreg.com

JHARDA USA L.L...

P.O. BOX 640, HOCKESSIN, DELAWARE 19707, USA PHONE: OFF: 001 302 234 8550

FAX: 001 302 234 7570



September 29, 2016

To: Whom it May Concern

Re: Sharda USA LLC EPA Company Number 83529

This letter serves as notification Sharda USA LLC has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as the Agent on our company's behalf regarding state and/or federal regulatory matters as determined by Sharda USA LLC. The following employees of Wagner Regulatory Associates, Inc. are authorized to act on our behalf:

Cheryl Wagner

Kt Woodall

Phone: 302-635-7289

Phone: 302-635-7279

Phone: 302-635-7283

Barbarette Young-Henry

Email: cheryl@wagnerreg.com

Email: barbarette@wagnerreg.com

Email: ktwoodall@wagnerreg.com

James Wagner

Email: james@wagnerreg.com

Phone: 302-635-7290

Anna Armstrong

Email: anna@wagnerreg.com

Phone: 302-510-0039

Carrie Nolan

Email: carrie@wagnerreg.com

Phone: 302-635-7632

Kari Albright

Email: kari@wagnerreg.com

Phone: 302-635-7281

Correspondence can be addressed to any of the above employees at:

Wagner Regulatory Associates P. O. Box 640

Hockessin, DE 19707-0640

Thank you for your time and assistance. Please feel free to contact Wagner Regulatory Associates should you have any questions.

Respectfully submitted,

Sharda USA LLC

Ashish Bubna (Director)

cc: WRA, Inc.

